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Intellectual property protection

Its role & benefits

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VACCINATE A CHILD
PROTECT A NATION

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Introduction

Patents and drug development are inextricably linked. Given the economics of the pharmaceutical industry, this is inevitable. Furthermore, many countries which have not previously had intellectual property (IP) laws and enforcement mechanisms in place have now signed the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) as members of the World Trade Organization. In order to be part of the international economic community, and in order to have significant participation in the pharmaceutical industry, a country must eventually implement and enforce intellectual property laws.

Some in the public health community have long felt that there is an inherent unfairness in the IP system, particularly in the area of vaccines. The administration of vaccines to a child can so dramatically enhance the quality of his life in an easy cost-effective way, and there is enormous frustration when access to even this minimal public health intervention is unattainable for extremely poor children. This is not to suggest that patents are the only potential short-term hurdle preventing wide distribution of vaccines in the developing world; the yellow fever vaccine, for example, has been slow to be adopted in all places it is needed, without patent protection. However, it is commonly felt that IP and its enforcement have prevented poor children from access to new vaccines, and as a concept, IP is sometimes mistrusted in the public health community. This perception is unfortunate, because it can foster distrust when partnership is far more likely to lead to the actual immunization of poor children with new vaccines. It is also counterproductive in that IP will be increasingly utilized and enforced for pharmaceuticals generally and for vaccines specifically. As a system, it is unavoidable.

IP is sometimes mistrusted in the public health community. This perception is unfortunate ...

A far more constructive way of dealing with IP is to learn to utilize IP mechanisms and the economics of vaccine production to the advantage of the public sector. This can be done via licensing of technology, creative royalty arrangements, upgrading of local manufacturing facilities (or conversely, closing down those that are inefficient or not able to meet quality standards). The public sector can

also better utilize the strength of volume purchases necessary for the world's poorest children. Simple advance notice of need and contractual agreements to purchase certain new vaccines in volume *over time* could foster better relations, perhaps more flexibility in prices and, ultimately, better access to new vaccines. In this way, the public health community can foster partnership with industry in a way which could have the ultimate effect of getting poor children immunized with vaccines like Hep B, long accessible to children in the developed world.

The nature of intellectual property

The patent system was devised to encourage two things: innovation and dissemination of technical information. In exchange for publication of his or her patent, the inventor is rewarded a limited monopoly, which offers the possibility of profit. The monopoly allows the patent holder to prevent others from making, using or selling a product which is patented or which results from the use of patented technology. The monopoly is limited as to time (now 20 years) and by national boundaries. The inventor can prevent others using the patented technology during the patent term, and only in the country (or countries) where the patent has been granted.

Patents are one of four main types of IP, the other three of which are copyrights, trademarks and know-how. Only patents and know-how will be considered in this paper. Know-how is essentially experience gained in working with a given technology and not disclosed publicly. This can include clinical and manufacturing records, manufacturing procedures as well as equipment and plant designs. It is far less tangible than a patent and, therefore, more difficult to enforce, although just as important to protect.

Patents and the royalties which they command do raise the price of vaccines in the short term, but not dramatically. For some vaccines, the percentage of price increase is negligible (e.g. Hib-0-2%). For others, it is slightly higher, (acellular pertussis-2-10%) To date, the price of the recombinant Hepatitis B vaccine is the most affected by royalty costs, at 13–15%. The more significant increment in vaccine price comes not from the royalty costs but from lack of competition during the patent period. Moreover, patents do not preclude the manufacture and marketing of competing products that do not infringe on the specific innovation protected by the patent.

The reasons for and the approaches to intellectual property protection

The first reason for protection is described above. The assumption is that innovation, and some financial risk-taking, is thereby encouraged. But there are other reasons to protect IP. Countries that tend to enforce IP foster their own research communities in other ways. For example, it is more likely that a company based in an IP respecting country will be able to enter technology transfer agreements with patent holders from other countries than it will be for one based in a country with a reputation for lax enforcement of IP laws. This is because of the obvious risk to the licensor's patent. Furthermore, scientists and other potential patent holders have an impetus to leave countries in which they do not feel they will be well remunerated for their innovations. It is more difficult for them to attract research monies into countries where the return on investment is unclear.

A potential investor in vaccine production ... will ... choose a country which respects and enforces IP

Another reason to protect IP at the national level is that failure to do so discourages investment from external sources. Given the choice, a potential investor in vaccine production, or that of anything else requiring IP, will, in all likelihood, choose a country which respects and enforces IP.

Intellectual property is protected at the national level because patents are granted at the national level. There is wide variance between countries in the extent to which it is applied and enforced. There are also cultural differences in the extent to which the concept of IP is accepted. However, a patent system cannot function effectively if enforcement is unlikely and potential violators of IP are aware that they can violate IP with impunity. If a country has a strong IP enforcement system in place, then inventors are more likely to file for patents there. If not, the inventor is likely to avoid the market for fear of piracy of his IP even if the market might be attractive otherwise.

Benefits to countries, institutions and individuals resulting from the protection of intellectual property

The benefit to countries is the increased likelihood of external investment described above. In addition, enforcing IP fosters domestic research activity. The benefits to institutions and to individuals are just as important. The jobs that naturally follow from outside investment in vaccine production tend to be high paying, desirable technical positions. This kind of employment obviously benefits individuals as well as employers and the society at large. Furthermore, the citizens of the country are more likely to have access to the fruits of innovation, not just in the area of vaccines, but other technologies as well.

The increasing role of intellectual property in biotechnology and vaccines

Vaccines are increasingly important in the pharmaceutical industry for many reasons. One is that the idea of prevention as opposed to therapeutic or curative care has become more important in the developed world due to changes in the health care system with greater emphasis on cost containment, including health maintenance organizations, and less on traditional fee-for-service care. Another factor is the rise of antibiotic resistant organisms. Immunotherapies are the subject of significant research and have resulted in the licensure of new immunological products. This research is not only in the area of communicable disease, but also for the treatment of many disorders, among them cancer, autoimmune diseases and allergies.

Very little of this research or innovation has come about without the use of the IP system. Without it there is little if any impetus to take the risk to develop the products in the first place. With the level of risk and investment required by the pharmaceutical industry—and vaccine producers in particular—growing rapidly, the role of IP is even more critical and integral to the development of new vaccines. This is not to say that people in countries which do not recognize IP don't have a right to these vaccines, but their governments may actually inadvertently hinder access to vaccines by their policies. They do so by discouraging investment generally, thereby lowering societal wealth and consequent ability to pay. Specifically, they may unintentionally do so by discouraging legal vaccine technology transfer and by failing to encourage domestic vaccine research and development. (Locally produced vaccine *may* be less expensive than vaccine imported and distributed, though quite possibly it may not be, given economies of scale and the cost, in both human and financial capital, of keeping a plant for a new vaccine up to good manufacturing practice standards).

The reality regarding successful access to new vaccine production technologies

There are several factors influencing a company's decision as to whether they will enter a technology transfer agreement. It is a given that a company will not enter an agreement with any entity which it believes does not (or cannot) have adequate experience and quality control in place. Vaccines are unlike other commodities in important ways. Currently, they tend to be administered ideally to entire birth cohorts of healthy children. As such, the ramifications of poor quality production can be profound. Vaccines are also credence goods, meaning that the consumer cannot independently assess the quality of the product. To some extent, the consumer must rely on his or her belief in the manufacturer's ability to make a quality product in making a choice as to whether to use that product. Given the level of risk involved to healthy children and the importance of reputation in the industry, no vaccine manufacturer wants to be affiliated or even associated with poor quality vaccine production. There is, of course, the risk of liability, but that is not so significant in the developing country context. But there is enormous risk in bad publicity from poor quality with the consequence of loss of credibility in all markets. Know-how protection and assurance of quality are therefore very important considerations for any vaccine technology patent holder to consider before entering into a technology transfer or manufacturing partnership agreement with any third party.

... no vaccine manufacturer wants to be affiliated or even associated with poor quality vaccine production

Trading intellectual property protection

Intellectual property rights can be traded like many other assets, by mutual agreement between partners. This being said, it is important to realize that for local manufacturers which are able to attain and sustain GMP as well as qualified staff, in a country which respects IP, the possibility exists that patent rights can be licensed. And local manufacturers can bring something to the table. They bring access to hitherto untapped markets.

Vaccine manufacturers located in developing countries need to be adept at dealing with patent holders in other countries. In order to conduct the necessary negotiations successfully, the local manufacturer must obtain good legal counsel well-versed in technology transfer and in the language used in the negotiation. Local manufacturers may otherwise have difficulty arguing their cases successfully to potential licensors, as well as protecting their own interests in the process. In order to do so, they must rely not only on qualified scientists, but on qualified attorneys as well.

Enforcement of intellectual property laws

For the creation of "partnerships", intellectual property holders, including industry, look to markets, technological capability and national respect for and enforcement of IP laws.

The poorer children of the world often do not have access to new vaccines. Historically, this is a function of the price of new vaccines (early in the life cycle) and an absence of distribution channels. The price is a function of the costs associated with development and regulatory licensing as well as the wealth of the markets in which the vaccine is sold. In order to encourage market entry via technology transfer the potential licensee must convince IP holders that:

1. There is a viable and untapped or underutilized market for a vaccine;
2. There is a local producer able to attain and maintain GMP;
3. There is a local producer that can produce the product for the market more cost effectively than it could be produced externally (e.g. in the licensor's home country);
4. The local producer will market its lower-production-cost product *only* within the designated markets; and
5. The local producer operates in a country which respects IP. In order for a licensor to enter a technology transfer agreement, that licensor must be convinced that such technology transfer will not only present limited risk but also financial benefit.

Market segmentation and tiered royalties

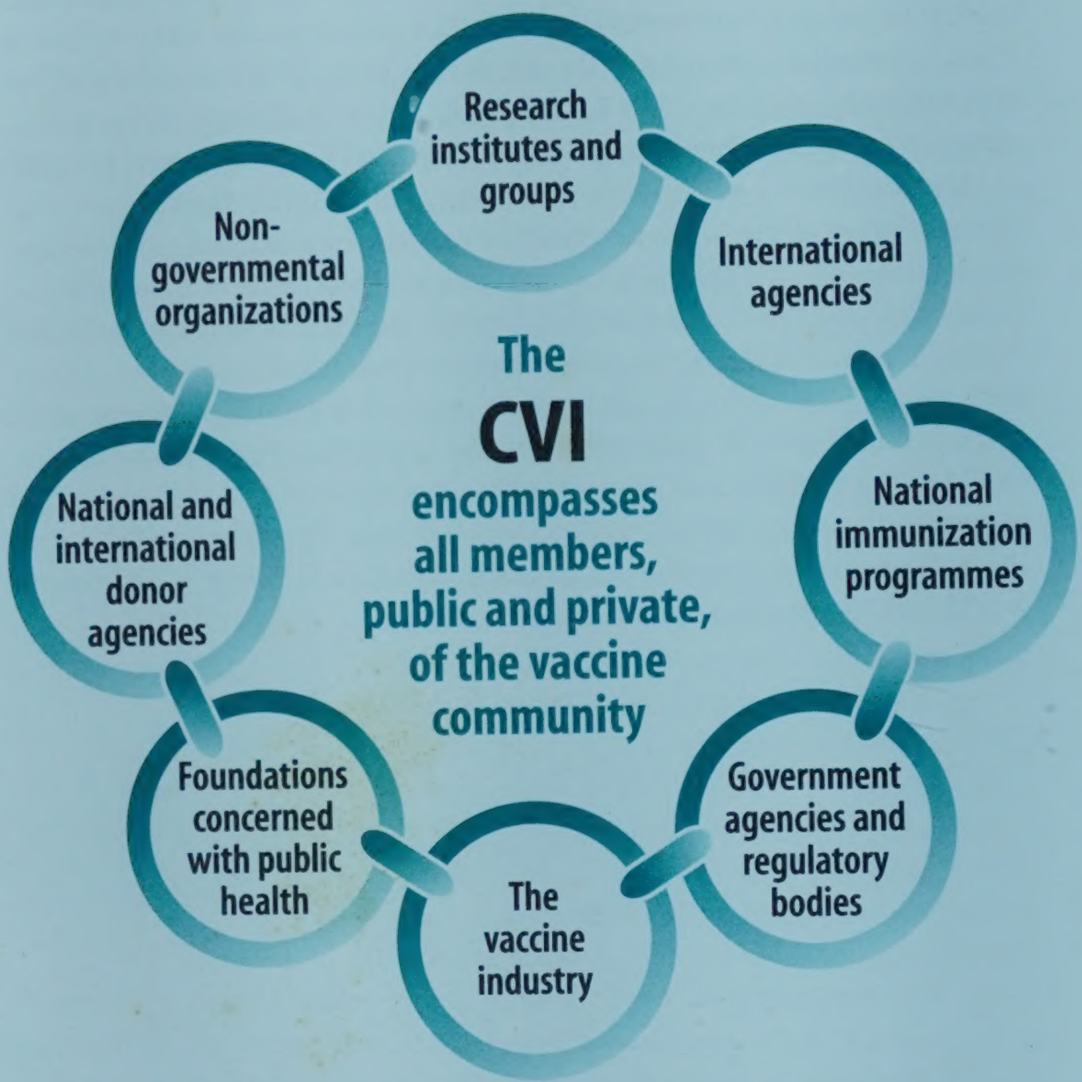
In licensing of IP, arrangements can include market segmentation and tiered royalties. Licensing of any intellectual property occurs with the hope of exploiting potential markets to the fullest. If licensors fear that their most profitable markets will be endangered by the existence of lower priced, yet comparable products coming from outside, they are unlikely to license their technology to producers in those outside markets. However, if potential licensors could be assured that the product would be sold only within the market designated in the licensing agreement, then they would consider licensing technology to producers for those markets. They would do so in order to increase market share, and to enjoy other advantages, e.g. improved distribution channels, knock-on effects for other products, improved public relations, etc. Another method by which introduction into low priced, high volume markets might be encouraged is building differences in actual production costs into the ultimate price of the vaccine. A licensor of technology might consider the receipt of a lower royalty in exchange for the entry of the licensee into markets he might not otherwise consider. This tiering of royalties in order to encourage market entry exists in other licensing contexts and could be utilized in the area of vaccines.[1] As stated above, royalty expenses are not generally a significant contributor to the cost of vaccines, but for large volume purchases by price-sensitive public sector buyers, this could provide some incentive to the licensee. The licensor would of course be motivated to reduce the royalty price by the possibility of incremental volume, i.e. sales volume he would not otherwise enjoy.

Tiering of royalties to encourage market entry could be utilized in the area of vaccines

[1] See draft WHO/CVI paper "Tiered royalties: one way to hasten the global introduction of new vaccines".

Conclusion

New vaccines will be covered by IP protection. This is an unavoidable reality in today's commercial world. The public sector has overcome many obstacles to successfully immunize 80% of the world's children and eradicate disease. This is simply another challenge. Even if it appears to hinder their access to vaccines in the short term, IP systems in the long term have shown their ultimate value in fostering innovation and the large financial investments required to develop ideas into safe and efficacious vaccine products, which eventually benefit all children. Fortunately, IP and the mechanisms by which it is traded and utilized are not insuperable obstacles to access. International IP mechanisms simply comprise another system which must be mastered in order to serve the pubic health needs of the world's poor children. If the system is understood and utilized by all interested parties, including the public sector, then perhaps the time lag between access to new vaccines in the developed and developing world can be shortened or even eliminated.


Research institutes and groups
International agencies
National immunization programmes
Government agencies and regulatory bodies
The vaccine industry
Foundations concerned with public health
National and international donor agencies
Non-governmental organizations
The
CVI
encompasses all members, public and private, of the vaccine community

The Children's Vaccine Initiative (CVI) is a global coalition of organizations from the public, nongovernmental and private sectors, including the vaccine industry, working together to maximize protection against infectious diseases through the development and utilization of safe, effective, easy-to-deliver and widely available vaccines.

Launched at the World Summit for Children in 1990, the CVI is co-sponsored by the United Nations Children's Fund (UNICEF), the United Nations Development Programme (UNDP), the World Health Organization (WHO), the World Bank and the Rockefeller Foundation.

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▸▸ Visit our web site at www.vaccines.ch